Remarks

Claims 1-40 are pending in this application. Claims 1-11 and 15-17 have been found allowable. Claims 12-14 and 18-40 are rejected, and Claims 12, 18, and 22 are objected to. Applicant herein amends claims 12, 14, 18, and 22, addressing the Examiner's concerns. No new matter is presented by way of these amendments to the claims.

Claim 14 is clear and definite.

Claim 14 stands rejected under 35 U.S.C. § 112, as allegedly being indefinite. Applicant herein amends claim 14, thereby rendering the rejection moot. Claim 14 is amended herein to indicate that "the concentration of stabilizing agent is 5-10%." Support for using a stabilizing agent at concentrations between 5-10% is found, for example, on page 7, line 21, and in Table 3 on page 31. For example, Table 2 shows results that demonstrate that a concentration of 10% of either sucrose or trehalose results in a retention of at least 40% of the antigenicity, activity, immunogenicity, or combination thereof as compared to an untreated reference sample that has not been subject to the evaporation process. Similarly, Table 2 provides results that demonstrate that sucrose at a concentration of as low as 3.15% sucrose also yields greater than 40% retention of antigenicity, activity, and/or immunogenicity. Thus, one of skill in the art would have understood from the data disclosed in the specification that as little 3.5% and at least as much as 10%, as well as the range between 3.15% and 10%, for example 5-10%, of a suitable stabilizing agent would result in the desired retention of properties. Applicant submits that these experimental results clearly demonstrate that preserving an antigen in the presence of a stabilizing agent, wherein the stabilizing agent is present at a concentration of between 5-10%, results in a retention of at least 40% of antigenicity, activity, and/or immunogenicity, as recited in amended claim 14. Therefore, Applicant respectfully requests that this rejection under 35 U.S.C. § 112 be withdrawn.

Provisional Obviousness-type double patenting

Claims 23-33 and 36-39 stand rejected as allegedly being unpatentable over claims 1-3, 6, 14, 15-18 and 20 of copending US Patent Application No. 10/533,464. US Patent Application 10/533,464 is the National Phase of PCT PCT/EP03/12160, filed 30

October 2003. As of the present date, no claims of US Patent Application No. 10/533,464 have been found to be allowable.

According to MPEP §804B "[i]f the 'provisional' double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent." In accordance with MPEP § 804B, the provisional double patenting rejection of claims 23-33 and 36-39 over US Patent Application No. 10/533,464 should be withdrawn. Should claims in US Patent Application No. 10/533,464 be deemed to be obvious over claims issued from the subject application (that is, one or more of claims 1-40 of US Patent Application No. 10/533,462), an obviousness-type double patenting rejection over the issued claims for this case would be appropriate in US Patent Application No. 10/533,464. However, it is not proper to maintain a provisional obviousness-type double patenting rejection of claims 23-33 and/or 36-39, or to require a terminal disclaimer in the present circumstances, because claims 23-33 and/or 36-39 are now in condition for allowance, and the claims of US Patent Application No. 10/533,464 have not yet issued. Accordingly, the rejection should be withdrawn.

Applicant's amendments render moot the objections of claims 12, 18 and 22.

The Examiner has objected to claims 12, 18 and 22 due to informalities. Applicant has amended claims 12, 18 and 22, as suggested by the Examiner, thus obviating these objections. Accordingly, Applicant respectfully requests that the objections be withdrawn.

Applicant's amendments render moot the rejections of claims 13, 19-21, 34, 35, 38 and 40 under 35 U.S.C. § 112

Claim 38 stands rejected under 35 U.S.C. § 112 as allegedly being indefinite. Applicant has amended claim 38 to clarify that the mixture of antigens can be either acellular or whole cell Diphtheria antigen, Tetanus antigen and Pertussis antigen. This is consistent with the use of the phrase "whole cell" in claim 37, from which claim 38 depends. Applicant believes that this amendment renders the rejection moot, and respectfully requests that the rejection be withdrawn.

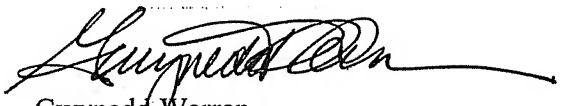
Claims 13, 19-21, 34, 35 and 40 stand rejected under 35 U.S.C. § 112 as being indefinite for depending from a rejected or objected to claim. Applicant respectfully

submits that the amendments to the claims obviate all rejections and objections of record, and requests that the rejection of claims 13, 19-21, 34, 35 and 40 be withdrawn.

Conclusion

On the basis of the amendments and remarks above, Applicant believes that the claims are now in condition for allowance. In the event that any substantive issues remain, Applicant hereby requests a telephonic interview with the Examiner prior to preparation of any additional written action. Accordingly, the Examiner is invited to contact the undersigned to arrange for an Examiner's interview, or to discuss the status of this application.

Respectfully submitted,



Gwynedd Warren
Attorney for Applicant
Registration No. 45,200

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-7241
Facsimile (610) 270-5090